LITE DEPALMA GREENBERG, LLC
Bruce D. Greenberg
570 Broad St, Suite 1201
Newark, NJ 07102
Tel: (973) 623-3000
Fax: (973) 623-0858
bgreenberg@litedepalma.com

HERRERA PURDY LLP
Nicomedes Sy Herrera (*pro hac vice* application to be filed)
Andrew Purdy (*pro hac vice* application to be filed)
Laura E. Seidl (*pro hac vice* application to be filed)
1300 Clay Street, Suite 600
Oakland, California 94612
Telephone: (510) 422-4700

GOLDSTEIN & RUSSELL, P.C.
Tejinder Singh (*pro hac vice* application to be filed)
7475 Wisconsin Avenue, Suite 850
Bethesda, Maryland 20814
Telephone: (202) 362-0636

Attorneys for Plaintiff-Relator Zachary Silbersher

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA,

ex rel. ZACHARY SILBERSHER,

Plaintiffs,

v.

JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, and BTG INTERNATIONAL LIMITED,

Defendants.

Civil Action No. 19-12107 (KM) (JBC)

Hon. Kevin McNulty, U.S.D.J.
Hon. James B. Clark, III, U.S.M.J.

SECOND AMENDED COMPLAINT FOR VIOLATIONS OF:

1. **THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. §§ 3729–3733; AND**
2. **THE FALSE CLAIMS ACTS OF THE PLAINTIFF STATES, COMMONWEALTHS, AND THE DISTRICT OF COLUMBIA**

Document electronically filed

TABLE OF CONTENTS

Plaintiff-Relator Zachary Silbersher ("Relator"), through his attorneys Lite DePalma Greenberg, LLC; Herrera Purdy LLP; and Goldstein & Russell, P.C., on behalf of the United States of America; the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, and Washington; the Commonwealths of Massachusetts and Virginia; and the District of Columbia (the foregoing states, commonwealths and the District of Columbia collectively, "the Plaintiff States"), for his Complaint against defendants Janssen Biotech, Inc. ("Janssen Biotech"), Janssen Oncology, Inc. ("Janssen Oncology"), Janssen Research & Development, LLC ("Janssen R&D") (Janssen Biotech, Janssen Oncology, and Janssen R&D together, "Janssen"); Johnson & Johnson ("J&J"); and BTG International Limited ("BTG") (Janssen, J&J, and BTG collectively, "Defendants"), alleges, based upon personal knowledge, relevant documents, and information and belief, as follows:

I. INTRODUCTION

A. Overview of Defendants' False Claims

1. This case arises under the *qui tam* provisions of the federal False Claims Act ("FCA"[1]), 31 U.S.C. §§ 3729-3733, and its state counterparts, which create civil liability when a defendant makes, or causes to be made, a false or fraudulent claim for payment to the government. The FCA is the government's primary civil tool to redress fraud on the public fisc, and it permits knowledgeable whistleblowers, such as Relator, to sue on the government's behalf. Like many FCA cases, this one is about overpriced prescription drugs.

2. The cost of prescription drugs is one of the most intractable problems facing the

[1] This Complaint includes many acronyms and terms of art. A glossary is appended to make the Complaint more user-friendly.

American healthcare system. While pharmaceutical manufacturers have advanced myriad rationalizations for soaring costs, it is beyond debate that one of the fundamental reasons prices stay high is that brand-name drug manufacturers use patents to prevent competitors from entering the market, enabling the brand-name manufacturers to charge inflated monopoly prices until the patents expire. Critically, the point of the patent system is not to grant inventors a perpetual monopoly; it is to allow them to benefit from their discoveries for a set period, while encouraging others to wait in the wings until competition is permitted. When drug patents expire, generic drug companies with proper approvals from the Food and Drug Administration ("FDA") can market similar medicines, which they typically offer at much lower prices. The onset of competition also brings the price of the brand-name drug down.

3. The powerful incentives to maintain monopoly pricing have caused many brand-name manufacturers to attempt to "evergreen" their patents by seeking new patents on brand-name drugs as the old ones expire. These new patents frequently are of questionable validity. Many seek to patent features or uses of the drug that are obvious in light of prior art or are otherwise not inventive or useful. When the United States Patent and Trademark Office ("Patent Office") concludes that a patent application is not valid, it will deny the application.

4. Sometimes, manufacturers attempting to extend their patent monopoly cross legal and ethical lines by engaging in deceptive conduct—for example, failing to disclose information during patent prosecution that would have caused the Patent Office to reject an application. When manufacturers dishonestly maintain their monopoly, they fraudulently impose massive costs on the U.S. healthcare system, which continues to pay the manufacturer inflated monopoly prices.

5. This is such a case. Defendants manufacture, sell, and distribute Zytiga® (abiraterone acetate), which doctors widely prescribe to patients with metastatic castration-resistant prostate cancer ("mCRPC"). In the United States, a one-month prescription of Zytiga typically costs over $9,000. Zytiga is covered by Medicare, Medicaid, and other government programs. The typical patient takes Zytiga for twelve to eighteen months, meaning that the government typically pays between $108,000 to over $160,000 in false claims for every patient who is prescribed Zytiga.

6. Defendants make over $2 billion each year selling Zytiga. Over $1 billion of such sales are made in the United States. Approximately 80% of prostate cancer patients in the United States are covered by Medicare. Plaintiff States' Medicaid programs also cover Zytiga. Additionally, the United States Government purchases Zytiga through numerous programs, including, without limitation, the Veterans Health Administration, the Military Health System, the Defense Health Agency / TRICARE, the Indian Health Service, the Federal Bureau of Prisons' Health Services Division, and the Coast Guard's Office of Health Services. Therefore, government funds pay a significant portion—indeed, the large majority—of Zytiga's annual sales in the United States. Government funds therefore disproportionately bear the burden of Zytiga's elevated, supracompetitive prices.

7. According to the Centers for Medicare & Medicaid Services ("CMS"), a federal agency within the United States Department of Health and Human Services ("DHHS"), Medicare Part D and Medicaid payments for Zytiga alone totaled approximately $877,587,632.97 in 2017 based on 93,665 claims. Medicaid payments totaled $42,903,803.24 in 2017 based on 5,067 claims. While 2017 is the latest year for which publicly-available data has been published regarding Medicare Part D and Medicaid payments for Zytiga, upon

information and belief, the amount of annual government payments or reimbursements for Zytiga has increased since then.

8. The chemical compound patent covering Zytiga—U.S. Patent No. 5,604,213 ("the '213 Patent")—expired on December 13, 2016. Defendants knew that at least fourteen generic manufacturers were ready, willing, and able to introduce generic competition to Zytiga when the '213 Patent expired. Such generic competition would have reduced the price of abiraterone acetate by at least 85%, and Defendants would have reasonably expected to lose 90% or more of Zytiga's market share. To protect their supracompetitive profits for abiraterone acetate—which patients dying of mCRPC desperately need—Defendants fraudulently obtained a patent to block generic entry after the expiration of the '213 Patent. The fraudulently obtained patent is U.S. Patent 8,822,438 (the '438 Patent).

9. Even though Defendants knew the fraudulent '438 Patent eventually would have been invalidated, the delay caused by Defendants' fraudulent course of conduct manipulating the regulatory structure for generic approval (described below) allowed Defendants wrongfully to shield over $1 billion in Zytiga revenue, most of it paid by federal and state government funds.

10. The Federal FCA and the State FCAs provide a mechanism for the federal and state governments to protect their health care funds from such unlawful predation. Relator brings this *qui tam* action to do so.

11. As set forth below, Defendants have knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval by the United States Government and each of the Plaintiff States in connection with the sale of Zytiga (each, a "False Claim"). These False Claims include, without limitation: (a) claims for Medicare and Medicaid

reimbursement for Zytiga prescriptions; and (b) claims for payment relating to government purchases of Zytiga under certain government healthcare programs, such as the Veterans Health Administration.

12. Defendants willfully made false and materially misleading statements to the United States Patent and Trademark Office ("Patent Office") fraudulently to obtain the '438 Patent, which was scheduled to expire in 2027 until it was invalidated. The '438 Patent was used by Defendants unlawfully to exclude generic alternatives to Zytiga from entering the market. As a result, Defendants have been able to charge artificially inflated prices for Zytiga and to charge for Zytiga when prescriptions would otherwise have been filled with a generic alternative.

13. These tremendous public expenditures are attributable to Zytiga's fraudulently inflated price, which tainted every claim for payment or reimbursement for Zytiga.

14. By systematically overcharging the United States and the Plaintiff States for Zytiga, Defendants violated the federal FCA, and false claims acts of the respective Plaintiff States. Each claim for reimbursement for Zytiga constituted a separate actionable violation of these laws.

15. Defendants' actions violate the Federal FCA and the following State FCAs: The California False Claims Act, Cal. Gov't Code §§ 12650–12656; Colorado Medicaid False Claims Act, Colo. Rev. Stat §§ 25.5-4-303.5 to -310; Connecticut False Claims Act, Conn. Gen. Stat. §§ 4-274 to -289; Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§ 1201-1211; District of Columbia False Claims Act, D.C. Code §§ 2-381.01 to .09; Florida False Claims Act, Fla. Stat. §§ 68.081–.09; Georgia False Medicaid Claims

Act, Ga. Code Ann. §§ 49-4-168 to 168.6; Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 to -31; Illinois False Claims Act, 740 Ill. Comp. Stat. 175/1–175/8; Indiana False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.5-1 to -18; Iowa False Claims Act, Iowa Code §§ 685.1–.7; Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §§ 46:437–:440; Maryland False Health Claims Act, Md. Code Ann., Health-Gen. §§ 2-601 to -611; Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, §§ 5A–5O; Michigan Medicaid False Claims Act, Mich. Comp. Laws. §§ 400.601–.615; Minnesota False Claims Act, Minn. Stat, §§ 15C.01–.16; Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 to -413; Nevada statute concerning Submission of False Claims to State or Local Government, Nev. Rev. Stat. §§ 357.010–.250; New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 to -18; New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 to -15, and New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 to -14; New York False Claims Act, N.Y. State Fin. Law §§ 187–194; North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 to -618; Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, §§ 5053–5053.7; Rhode Island False Claims Act, R.I. Gen. Laws §§ 9-1.1-1 to -9; Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 to -185; Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001–.132; Vermont False Claims Act, Vt. Stat. Ann. tit. 32, §§ 630–642; Virginia Fraud Against Taxpayers Act, Va. Code §§ 8.01-216.1 to .19; and Washington State Medicaid Fraud False Claims Act, Wash. Rev. Code §§ 74.66.005–.130.

II. PARTIES

16. The Relator, Zachary Silbersher, is a citizen of the State of New York. Relator is a patent attorney whose practice focuses on investigating invalid pharmaceutical patents that brand

manufacturers use to protect their drugs from price competition. He also operates a consulting firm, Markman Advisors, which provides patent analysis for its clients. Through his independent investigation, Relator has uncovered information supporting the claims set forth herein. Relator's independent research and investigation has generated information that is independent of, and materially adds to, any publicly-disclosed allegations and transactions.

17. Relator is an "original source" of information within the meaning of 31 U.S.C. § 3730(e)(4)(B) and all applicable State FCAs. On November 2, 2018 and June 5, 2019, Relator voluntarily provided the information on which the allegations or transactions alleged herein are based to the Federal Government and the Plaintiff States before filing this action. Moreover, Relator provided independently-obtained information that materially adds to any previous public disclosure of any aspect of the fraud alleged herein. Among other information, Relator has provided facts demonstrating that Defendants failed to disclose to the Patent Office that one of its competitors had not received FDA approval during the time period for which Defendants were making critical market share comparisons between Zytiga and its biggest competitor, Xtandi®. Relator has also provided facts demonstrating that Defendants withheld material information from the Patent Office that the claimed commercial success of Zytiga lacked any nexus to the claimed invention in the '438 Patent.

18. Relator seeks to recover all available damages, civil penalties, and other relief for federal and state-law violations alleged herein. In particular, Relator sues to recover on behalf of the United States Government and its various agencies administering government-funded health care programs, including, without limitation, Medicare; Medicaid; CHIP; the Indian Health Service; the Federal Bureau of Prisons' Health Services Division; the Veterans Health Administration; the Military Health System; the Defense Health Agency / TRICARE;

and the Coast Guard's Office of Health Services. Relator also sues to recover on behalf of the Plaintiff States and their respective agencies administering state programs for prescription drug coverage, including, without limitation, Medicaid contributions.

19. Defendant Janssen Biotech, Inc., is a corporation organized and existing under the laws of Pennsylvania, with its principal place of business at 800/850 Ridgeview Drive, Horsham, PA 19044. Janssen Biotech is a wholly-owned subsidiary of Johnson & Johnson ("J&J").

20. Defendant Janssen Oncology, Inc., is corporation organized and existing under the laws of Delaware, with its principal place of business at 10990 Wilshire Boulevard, Los Angeles, CA 90024. Janssen Oncology is a wholly-owned subsidiary of J&J.

21. Defendant Janssen Research & Development, LLC, is a limited liability company organized and existing under the laws of the State of New Jersey, with its principal place of business at 920 Route 202 South, Raritan, New Jersey 08869. Janssen R&D is a wholly-owned subsidiary of J&J.

22. Defendant Johnson & Johnson ("J&J") is corporation organized and existing under the laws of the State of New Jersey, with its principal place of business of One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. J&J is the parent corporation of the Janssen entities and filed false, misleading, and fraudulent documents with the USPTO in connection with the '438 Patent in concert with the other Defendants in furtherance of Defendants' collective efforts improperly to exclude generic competitors through the scheme alleged herein. Through its wholly-owned subsidiary Cougar Biotechnology, J&J also holds the rights to the '213 Patent, which originally protected Zytiga's chemical compound and expired in December 2016.

23. Defendant BTG is a company organized and existing under the laws of the United Kingdom, with its principal place of business at 5 Fleet Place, London, EC4M 7RD United Kingdom.

24. Defendants sell Zytiga in the United States pursuant to New Drug Application ("NDA") No. 202379, which has been approved by the FDA.

25. Janssen Oncology is an owner of the '438 Patent, entitled "Methods and Composition for Treatment of Cancer," as issued by the United States Patent and Trademark Office on September 2, 2014. As set forth below, BTG asserts co-ownership of the '438 patent along with Janssen.

26. Janssen Biotech is the holder of NDA No. 202379. Janssen R&D works in collaboration with Janssen Biotech with respect to NDA No. 202379.

III. JURISDICTION AND VENUE

27. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. §§ 3730(b)(1) and 3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. In addition, 31 U.S.C. § 3732(b) specifically confers jurisdiction on this Court over the state law claims.

28. Under 31 U.S.C. § 3730(e), and under the comparable provisions of the Plaintiff State statutes, there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. Moreover, whether or not such a disclosure had occurred, Relator would qualify as an "original source" of the information in this Complaint, even had such a public disclosure occurred. Relator has direct and independent knowledge of the information on which the allegations herein are based; such knowledge materially adds to any publicly disclosed allegations or transactions; and Relator voluntarily provided the information

to the Government before filing this action and before any public disclosure of the allegations and transactions in this Complaint material to the false claims alleged herein.

29. This Court has personal jurisdiction over each of the Defendants pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process. Moreover, each of the Defendants entities maintain minimum contacts with the United States, and they all can be found in and transact business in this District.

30. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because Defendants can be found in and transact business in this District. At all times relevant to this Complaint, each of the Defendants regularly conducted substantial business within this District and made significant sales within this District. Moreover, numerous acts violating 31 U.S.C. §§ 3729-3733 occurred in this District, and a substantial part of the events giving rise to the claims alleged herein occurred here. Finally, J&J maintains its headquarters in this District.

31. Many of the acts underlying the false claims allegations herein occurred in this District, and thousands of False Claims were submitted in this District relating to Zytiga sales made within this District.

IV. FEDERAL AND STATE-FUNDED HEALTH CARE PROGRAMS

32. Government-funded health care programs cover medical services and prescriptions for one-third of the United States population.

A. Medicare

33. Medicare is a federally-funded health insurance program primarily benefitting the elderly. Medicare was created in 1965 when Title XVIII of the Social Security Act was adopted. The Medicare program is administered by CMS.

34. The Medicare program has four parts. Medicare Part A, the Basic Plan of Hospital Insurance, covers the cost of inpatient hospital services and post-hospital nursing facility care. Medicare Part B, the Voluntary Supplemental Insurance Plan, covers the cost of services performed by physicians and certain other health care providers, both inpatient and outpatient, if the services are medically necessary and directly and personally provided by the provider. Medicare Part C covers certain managed care plans. Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

35. Medicare provides benefits for patients being treated with Zytiga.

36. Medicare Part D prices are particularly susceptible to unlawful inflation compared with other government programs because there is no set ceiling price. Instead, Medicare Part D sponsors will typically negotiate prices that are directly affected by market prices that are inflated through the exclusion of competitors. The price for drugs paid by Medicare Part D are typically much higher than the price paid by the government for other programs and generally range from 130% to over 150% of the listed price on the Federal Supply Schedule. In negotiating and setting prices, Medicare sponsors will usually factor in the drug's price listed on the Federal Supply Schedule.

37. Many Medicare Part D prescription drug plans also require Step Therapy as a utilization management restriction that requires covered patients to first try less expensive alternatives (which would include generic drugs or cheaper biosimilars) before the plan will cover more expensive drugs. By unlawfully excluding competitors from introducing less-expensive generics through the assertion of the fraudulently-obtained patents in this case, Defendants have caused the filling of prescriptions for Zytiga that would have been filled with less-expensive generics, had they been available.

B. Medicaid

38. Medicaid is jointly administered by the United States and each state.

39. Individual state Medicaid programs are administered by each state, subject to oversight by the United States in accordance with statutes and with regulations promulgated by the Secretary of the DHHS. Pursuant to these statutes and regulations, the United States provides financial assistance to each of the state Medicaid programs by providing each state with financing equal to at least 50% of the costs incurred by the state Medicaid programs. In some instances, the United States pays for up to 75% of program costs incurred, including the costs incurred for reimbursing providers for dispensing prescription drug products (such as Zytiga) to Medicaid beneficiaries.

40. Each state Medicaid program obtains federal financial assistance by submitting quarterly claims to the United States for costs incurred administering the state Medicaid programs.

C. Other Government-Funded Health Programs

41. The other major government-funded health programs—including CHIP; the Indian Health Service; the Federal Bureau of Prisons' Health Services Division; the Veterans Health Administration; the Military Health System; the Defense Health Agency / TRICARE; and the Coast Guard's Office of Health Services—purchase significant amounts of Zytiga for their covered patients.

V. THE REGULATORY STRUCTURE THAT DEFENDANTS MANIPULATED TO BLOCK GENERIC COMPETITORS TO ZYTIGA

A. The Regulatory Structure for Approval of Generic Drugs

42. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a manufacturer must obtain FDA approval to sell a new drug by filing a New Drug Application ("NDA"). 21

U.S.C. §§ 301-392. An NDA must include submission of specific data concerning the safety and effectiveness of the drug. An NDA must also identify any patent that allegedly claims either the approved drug or approved methods of use of the drug that could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug prior to the expiration of the listed patent(s). 21 U.S.C. § 355(a), (b). When the FDA approves an NDA, it publishes the patents identified by the brand manufacturer in a database called "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." Patents issued after NDA approval may be listed in the Orange Book within thirty days of issuance. 21 U.S.C. § 355(b)(1), (c)(2).

43. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, because the agency does not have the resources or authority to verify the manufacturer's patents were not procured through fraud. In listing patents in the Orange Book, the FDA merely performs a ministerial act. Therefore, pharmaceutical companies that list patents in the Orange Book that they claim protect a particular drug have a duty to list only those patents they believe in good faith restrict generic entry.

B. The Hatch-Waxman Amendments

44. The Hatch-Waxman Amendments to the FDCA, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. (1984). A generic manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA. An ANDA applicant must demonstrate that the proposed

generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. *See generally* 21 U.S.C. § 355(j) *et seq.* To do so, an applicant must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug. Additionally, an applicant must prove that the generic drug is absorbed at the same rate and to the same extent as the brand drug.

45. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration, dosage and form, and meeting applicable standards of strength, quality, purity and identity are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug is absorbed at the site of drug action to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B). Thus, a generic drug is identical to a brand name drug in dosage, form, safety, strength, route of administration, and intended use.

46. Generic drugs that are therapeutically equivalent to their brand counterparts are given an "AB" rating by the FDA, allowing their substitution for the brand when a patient presents a prescription for the brand product.

47. Congress enacted the Hatch-Waxman Amendments to expedite the entry of generic competitors, thereby reducing healthcare expenses nationwide. As a result, generic drugs became an increasingly large part of prescription drug revenues and a growing threat to brand name drug profits. In 1984, prescription drug revenue for brand and generic drugs totaled $21.6 billion, with generic drugs accounting for 18.6% of total prescriptions. By 2013, total prescription drug revenue had climbed to more than $329.2 billion, with generic drugs

accounting for 84% of prescriptions. *See* IMS Institute for Healthcare Informatics, *Medicine and Shifting Costs of Healthcare* 30, 51 (2014).

C. Paragraph I, II, III, and IV Certifications

48. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications for each Orange Book-listed patent:

a. That no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

b. that the patent for the brand drug has expired (a "Paragraph II certification");

c. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

d. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

49. Because ANDAs with Paragraph I, II, or III certifications face no potential patent challenge, FDA approval of these ANDAs is relatively quick and expeditious.

50. However, when a generic manufacturer is forced to file a Paragraph IV certification because the Orange Book lists a patent that has not or will not expire by the time of the planned generic entry, the brand manufacturer is able trigger extensive regulatory delays that will block FDA approval of generic entry—potentially for many years. Moreover, the filing of Paragraph IV certifications and the resulting patent infringement actions delay ANDA

approval by the FDA and divert resources from prompt ANDA approval and the introduction of generic alternatives into market.

51. When a generic manufacturer files a Paragraph IV certification, it must promptly provide notice to the brand manufacturer. Filing an ANDA with a Paragraph IV certification gives rise to a cause of action for patent infringement regardless of the merits of the action. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of thirty months from the notification date, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval" but cannot authorize the generic manufacturer to go to market with its product. Tentative approval means the ANDA would be ready for final approval but for the 30-month stay. As a practical matter, the initiation of a patent infringement action provides the brand manufacturer with the equivalent of an automatic 30-month injunction that prevents the generic manufacturer from releasing a competing generic product, regardless of the merits of the infringement action.

D. United States Patent Law

52. United States patents grant the patent owner or assignee the exclusive right to exclude others from practicing the patent product for a fixed period of time from the patent's priority date.

53. Under applicable patent law, an application for a patent will be rejected by the Patent Office if the invention was "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed

invention." 35 U.S.C. § 102. Even if the invention was not disclosed in detail as set forth in § 102, a claim is unpatentable if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. 35 U.S.C. § 103. If the Patent Office uncovers prior art that satisfies sections 102 or 103, it establishes a *prima facie* case of obviousness. To overcome a *prima facie* case of obviousness, the patent applicant has a number of options, including: (i) narrowing the invention to distinguish over the prior art; (ii) arguing the prior art does not render the claim obvious; or (iii) submitting objective evidence of secondary considerations, including commercial success, long-felt but unsolved need, and failure of others. A person or entity can challenge the validity of an issued patent by filing a petition for *inter partes* review with the PTAB. 35 U.S.C. § 311.

54. A patent applicant has an affirmative duty of candor and good faith when prosecuting a patent application, which includes an affirmative duty to disclose all material prior art known to the applicant at the time of the application. 37 C.F.R. § 1.56. Failure to disclose material prior art can render a patent unenforceable. *See e.g.*, *C.R. Bard, Inc. v. M3 Sys.*, 157 F.3d 1340, 1367 (Fed. Cir. 1998) ("Fraud in obtaining a United States patent is a classical ground of invalidity or unenforceability of the patent."). Moreover, concealing a material fact in a matter within the jurisdiction of a federal executive agency is a criminal offense punishable by fine and imprisonment. 18 U.S.C. § 1001.

E. The Economic Benefits of Blocking Generic Entry, Even When Frivolous

55. Therapeutically equivalent (or AB-rated) generic drugs contain the same active ingredient—and are determined by the FDA to be just as safe and effective—as their branded counterparts. The only material difference between generic drugs and branded drugs is their

price: when multiple generic drug manufacturer competitors enter the market for a given branded drug, generic drugs cost, on average, 80%-85% lower than the branded drug prior to generic entry. Moreover, the Federal Trade Commission ("FTC") estimates that about one year after market entry, a generic drug takes over 90% of the branded drug's unit sales.

56. When multiple generics enter the market, competition accelerates, and prices drop to their lowest levels. Competition from several generic sellers drives drug prices down toward marginal manufacturing costs. Defendants prevented this from happening with Zytiga by applying for and obtaining the '438 Patent

57. In the majority of states, pharmacists may (and in some cases are required) by statute or regulation to substitute a therapeutically equivalent generic drug with a brand-name drug—even when a prescription lists a brand-name drug—unless the prescription specifically prohibits such substitution. The Office of Inspector General of the DHHS has determined that generic drugs are dispensed 89% of the time when generic substitutes were available.

58. Zytiga was originally approved by the FDA in the chemo-refractory mCPRC market on April 28, 2011, and its FDA-approved exclusivity expired no later than April 28, 2016. Because at least fourteen generic manufacturers were willing and able to enter the market when the '213 Patent expired in December 2016, Defendants had a strong incentive to manipulate the regulatory structures to prevent generic entry. Even if Defendants listed a fraudulently-obtained patent in the Orange Book—one that Defendants knew would be invalidated in court or through *inter partes* review ("IPR")—the 30-month stay and the delay caused by forcing generic manufacturers to file Paragraph IV certifications and litigate infringement actions allowed Defendants to reap over $2.5 billion in Zytiga sales at supracompetitive prices. A significant portion of these sales have been paid for with

government funds through Medicare, Medicaid, and other programs.

VI. ALLEGATIONS CONCERNING DEFENDANTS' FALSE CLAIMS

A. Defendants' Patent Exclusivity for Zytiga Should Have Ended in December 2016

59. Zytiga (abiraterone acetate) is indicated in combination with prednisone for the treatment of patients with mCRPC, a form of prostate cancer. Abiraterone acetate works by suppressing the synthesis of testosterone. Co-administration with prednisone counters abiraterone acetate's side-effects, such as increased risk of hypertension.

60. Defendants jointly collaborate in the development, manufacture, sale and distribution of Zytiga.

61. By April 2016, Zytiga's FDA-approved exclusivity expired.

62. On December 16, 2016, the '213 Patent, which protected the chemical compound for Zytiga (abiraterone acetate), expired.

B. Defendants' Fraudulent Prosecution of the '438 Patent

63. The Patent Office allowed the '438 Patent because of false and misleading statements Defendants made during the patent's examination. Under applicable patent law, an application for a patent will be rejected by the Patent Office if the Patent Office uncovers prior art that shows the claimed invention to be obvious. By doing so, the Office establishes a *prima facie* case of obviousness. To overcome a *prima facie* case of obviousness, the patent applicant has a number of options, including: (i) narrowing the invention to distinguish over the prior art; (ii) arguing the prior art does not render the claim obvious; or (iii) submitting objective evidence of secondary considerations.

64. The Patent Office originally rejected the '438 Patent application as obvious over the prior art.

65. To overcome that rejection, Defendants represented to the Patent Office that certain "secondary considerations" purportedly demonstrated that Zytiga was a commercial success. But Defendants' submissions to the Patent Office were false, misleading, and misrepresentative of Zytiga's actual commercial success.

66. Secondary considerations of non-obviousness can come in many different forms. The most common forms are, *inter alia*: (a) the invention has achieved commercial success resulting from the supposedly patentable subject matter; (b) the invention satisfies a long-felt but unsolved need; (c) or the invention yields unexpected and surprising results. In each case, the patent applicant argues that even if a *prima facie* case of obviousness exists, the patent nevertheless should be allowed based on a secondary consideration of non-obviousness. Evidence of commercial success is significant only if there is a nexus between the claimed invention and the commercial success. If the feature creating the commercial success is not due to the patented invention, then the success is not pertinent. This is well-known by practitioners in the field, particularly Defendants, who have large and well-funded internal legal departments with access to significant and highly-qualified outside counsel.

67. In this case, Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research & Development, LLC filed certifications that they all were real parties-in-interest for the '438 Patent, and that all of them were wholly-owned subsidiaries of defendant J&J, which was also a party-in-interest to the '438 Patent application.

68. The '438 Patent resulted from a lengthy prosecution before the Patent Office. It began in February 2011 when Defendants filed patent application number 13/034,340 (the "'340 Application"). The '340 Application eventually resulted in the issuance of the fraudulently obtained '438 Patent. The proposed invention claimed a method for treating

prostate cancer through co-administration of abiraterone acetate and prednisone (a corticosteroid).

69. The original named inventors of the '340 application were Alan H. Auerbach and Arie S. Belldegrun. The '340 application was originally Janssen Oncology, Inc. Janssen Oncology was at all times relevant to this action a wholly-owned subsidiary of J&J. Janssen Oncology previously identified both itself and J&J as real-parties-in-interest with respect to the '438 patent, including during petitions for *inter partes review* of the patent.

70. J&J controlled prosecution of the '340 application. The Application Data Sheet (ADS) filed in connection with the '340 application on February 24, 2011 identified the applicants as Auerbach and Belldegrum. The ADS identified the mailing addresses for both Auerbach and Belldegrum, as applicants, at One Johnson & Johnson Plaza, New Brunswick NJ 08933. The customer number identified on the ADS was 27777, which corresponds to Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick NJ 08933-7003, which is the principal address for the publicly-traded company, John & Johnson. The email address identified on the ADS was jnjuspatent@corus.jnj.com. The ADS was signed by Andrea Jo Kamage.

71. During prosecution of the '340 application, J&J signed all responses to the Patent Office. For instance, on December 21, 2011, applicants for the '340 application filed the first substantive response to a prior restriction requirement. The response was signed by Andrea Jo Kamage on behalf of Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, NJ 08933-7003, Customer No. 27777. On June 4, 2013, applicants for the '340 application filed the Office-Action response containing the allegedly fraudulent statements (as discussed in more detail below). The response was signed by Andrea Jo Kamage on behalf of Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, NJ 08933-7003, Customer No. 27777.

72. During the Hatch-Waxman lawsuits in which Defendants asserted the '438 patent against proposed generics for Zytiga, Defendants' complaints alleged that Janssen Biotech, Janssen Oncology and Janssen Research & Development collectively "sells" Zytiga in the United States pursuant to NDA No. 202379.

73. Defendants' complaints further alleged that Janssen Biotech is the holder of NDA No. 202379, and Janssen Research & Development works in collaboration with Janssen Biotech with respect to NDA No. 202379. *See e.g., BTG Int'l Ltd. v. Actavis Labs. FL, Inc.*, Case No. 15-cv-05909 (D.N.J.) (Dkt. 1 ¶¶ 54-55). Zytiga is publicly sold and distributed by Janssen Biotech.

74. Janssen Oncology and Janssen Biotech are both wholly-owned subsidiaries of J&J. Janssen Research & Development is an indirect wholly-owned subsidiary of J&J because it is a wholly-owned subsidiary of Centocor Research & Development, which is a wholly-owned subsidiary of Janssen Biotech. *See BTG Int'l Ltd. v. Amneal Pharmaceuticals, LLC*, Case No. 19-1147 (Fed. Cir.) (Dkt. 62).

75. The Patent Office repeatedly rejected Defendants' '340 Application on the ground that co-administering abiraterone acetate with prednisone to treat prostate cancer was obvious in light of the prior art. To overcome this rejection, Defendants submitted fraudulent and misleading evidence they misrepresented to the Patent Office as demonstrating Zytiga's commercial success attributable to the claimed invention.

76. On February 3, 2012, the Patent Office rejected Defendants' '340 Application on the ground that the claimed invention was obvious based on prior art.

77. On July 3, 2012, J&J, on behalf of Defendants, submitted to the Patent Office purported evidence of Zytiga's commercial success. Defendants' July 3 submission asserted that Zytiga enjoyed commercial success because, within the first year of its release, "worldwide sales were over $400 million." Defendants, however, did not attempt to

demonstrate that the purportedly high sales amount were related, or had the requisite nexus, to the claimed patentable subject matter of the '340 Application, as required.

78. On or about September 11, 2012, the Patent Office once again rejected Defendants' submission and affirmed that the claims in the '340 Application were obvious in light of the prior art: "It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ both prednisone and abiraterone acetate, in the dosage herein claimed, together in a method of treating prostate cancer, including refractory prostate cancer."

79. The Patent Office also rejected Defendants' claim of commercial success based on the amount of Zytiga sales, because even a high amount of net sales after initial product launch is insufficient, by itself, establish commercial success or the required nexus with the claimed patentable subject matter. Thus, the Patent Office determined that Defendants' arguments concerning "commercial success have been considered, but are not found persuasive." The Patent Office informed Defendants, to have their application granted, they could not rely solely on gross sales figures without providing "evidence as to market share."

80. In rejecting Defendants' application, the Patent Office said:

> Furthermore, gross sales figures do not show commercial success absent evidence as to market share, *Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 226 USPQ 881 (Fed. Cir. 1985), or as to the time period during which the product was sold, or as to what sales would normally be expected in the market, *Ex parte Standish*, 10 USPQ2d 1454 (Bd. Pat. App. & Inter. 1988). In the instant case, there is no evidence of commercial success was provided.

Defendants therefore were on notice that a showing of commercial success would require information concerning the successful capture of market share, relevant time period, and what sales would normally be expected without the claimed invention.

81. In particular, the courts and the Patent Office look to evidence of *increasing* market share and the maintenance of such shares in the face of competitors and other adverse market forces, unless competitors' market entry was precluded or hindered for reasons other than the merits of the claimed invention (*e.g.,* because of blocking patents). *See, e.g.*, *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 740-41 (Fed. Cir. 2013); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 291 (Fed. Cir. 1985). Defendants knew that the only way the Patent Office would approve the '340 Application was to demonstrate that Zytiga's market share increased or were maintained against competing products as a result of the claimed invention in the '340 Application (*i.e.*, the co-administration of abiraterone acetate and prednisone).

82. In response to the Patent Office's latest rejection of the '340 Application, on June 4, 2013, J&J submitted additional materials on behalf of Defendants that Defendants represented to be truthful evidence demonstrating Zytiga's commercial success as a result of the invention claimed in the '340 Application. The only additional evidence that Defendants provided that related to a purported *increase* in Zytiga's market share involved chemo-naïve mCRPC patients. For this sub-market, Defendants made the following misleading and fraudulent statements, contrary to Defendants' duty of candor and good faith owed to the Patent Office:

> [S]hortly after its approval for chemo-naïve patients in December 2012, ZYTIGA had a market share of 15%. As of April 2013, ZYTIGA's market share was 20%, higher than two other available therapies, docetaxel and XTANDI, and approaching the market share of bicalutamide, a drug first approved in 2001 for prostate cancer.

83. Because chemo-naïve patients comprised over 70% of the mCRPC market, Defendants told the Patent Office that Zytiga's total market share in the mCRPC market increased approximately 3% from December 2012 to April 2013 (despite Zytiga's market share decline in the chemo refractory submarket).

84. Defendants' representations to the Patent Office concerning Zytiga's share of the mCRPC market was misleading and fraudulent. They fell well below the level of good-faith and candor required from patent applicants.

a. Defendants' statement was fraudulent and misleading because Xtandi had not been approved by the FDA for chemo-naïve mCRPC patients between December 2012 and April 2013. In fact, Xtandi would not be approved for chemo-naïve patients until September 2014. Xtandi is Zytiga's principal competitor in the mCPRC market. Indeed, even though Xtandi was not approved for the respective chemo refractory and chemo-naïve markets until after Zytiga, Xtandi overtook Zytiga in market share and number of prescriptions written by the end of 2015. For the chemo naïve market, Xtandi's market share quickly surpassed Zytiga's market share shortly after Xtandi's FDA approval in the chemo-naïve submarket. Approximately 16 months after Xtandi's FDA approval for the chemo-naïve submarket, Xtandi had overtaken Zytiga as the dominant drug for chemo-naïve mCRPC patients and for mCRPC patients overall.

b. Defendants' misrepresentation concerning Zytiga's performance against its primary rival, Xtandi, was knowing and intentional. In the same submission, Defendants acknowledged that Zytiga's patient market share in the chemo refractory mCRPC market had plummeted from 70% in July 2012 to 57% by April 2013. Defendants explained the drop in Zytiga's market share, in part, by the fact that Xtandi had been approved by the FDA for chemo-refractory mCRPC patients in August 2012, and thus was available to compete with and take market share away from Zytiga.

c. Defendants' reference to Xtandi's FDA approval in August 2012 for the chemo refractory mCRPC market—the specific market for which Defendants were trying to

explain a drop in Zytiga's market share—demonstrates Defendants' knowledge concerning the importance of FDA approval for specific indications in which market shares are being compared.

d. Moreover, in attempting to demonstrate Zytiga's increasing "market share" in the chemo-naïve mCRPC market, Defendants reported data from December 2012 through April 2013. In contrast, Defendants reported data for the chemo-refractory market starting in July 2012. Defendants justified their decision to provide the Patent Office with "market share" data having different starting time periods (as between the chemo refractory and chemo-naïve markets) by emphasizing that, whereas Zytiga obtained FDA approval for the chemo refractory market in April 2011, Zytiga did not obtain FDA approval in the chemo-naïve market until December 2012. This demonstrates that Defendants knew that the date of FDA approval was a material consideration when assessing the strength of a drug's market share in a relevant market segment. Defendants took great pains to emphasize the precise dates when Zytiga was approved for the chemo refractory and chemo-naïve markets and adjusted their data to fit the relevant starting time periods, because Defendants knew that accurate FDA-approval dates were important considerations when assessing the strength of a drug's comparative market share. Nevertheless, Defendants willfully withheld Xtandi's relevant FDA approval dates to the Patent Office, even though Defendants knew that such an omission made their submission materially false and misleading, and even though Defendants' duties of candor and good faith required Defendants to disclose it.

e. Defendants' representations to the Patent Office concerning Zytiga's "market share" are also misleading because, upon information and belief, the "market share" percentage that Defendants provided to the Patent Office were based on Zytiga's *patient*

market share, not its direct sales market share compared with other competing drugs. This is misleading and contrary to Defendants' duty of candor and good faith, because patients suffering from prostate cancer often take many drugs. Because such a "market share" figure measures the percentage of patients who are prescribed the drug, and *not* the market share of a drug based on its actual sales compared with sales of competing products, the total patient market share can substantially *exceed* 100%. In fact, it was well-known by people skilled in the art—but not disclosed to the Patent Office—that mCRPC patients typically build a tolerance to one drug, and move to another. Therefore, Defendants' use of patient share data when representing to the Patent Office that "shortly after its approval for chemo-naïve patients in December 2012, ZYTIGA had a market share of 15%. As of April 2013, ZYTIGA's market share was 20%, higher than two other available therapies, docetaxel and XTANDI" was fraudulent and misleading.

f. Defendants' representations to the Patent Office concerning Zytiga's "market share" in the chemo-naïve mCRPC market is also misleading because Zytiga's supposedly increasing "market share" was compared with the declining market share of bicalutamide, an older anti-androgen drug. This was a misleading comparison. Since at least 2010, the medical profession and those skilled in the relevant arts knew that bicalutamide lowered prostate-specific antigen ("PSA") levels without materially increasing survivability. Therefore, by 2012, bicalutamide was increasingly being prescribed in the chemo-naïve mCRPC market only for specific purposes in conjunction with treatment that was considered to be more efficacious. Particularly in light of Defendants' use of "patient" share data as a proxy for "market share," Defendants' comparison of Zytiga with bicalutamide to purportedly demonstrate that Zytiga's market share was increasing against competitors (such as

bicalutamide) by reason of the claimed invention (co-administration of abiraterone acetate with prednisone) was misleading. Defendants knew the facts that made such comparison misleading but willfully failed to inform the Patent Office of such facts.

85. Relying on Defendants' misrepresentation concerning Zytiga's growth in the chemo-naïve mCRPC market, the Patent Office issued a Notice of Allowance for the '340 Application, which led to the issuance of the '438 Patent. The sole reason that the Patent Office gave for allowing the '438 Patent—despite its prior rejections on the ground that the claimed invention was obvious in light of the prior art—was because of the (misleading) evidence that Defendants submitted concerning Zytiga's supposed commercial success. As the Patent Office explained in granting Defendants' application, the "commercial success of the combination of prednisone and abiraterone to treat prostate cancer obviate the rejection under 35 USC 103(a)."

86. The Patent Office had previously rejected Defendants' proffer of commercial success because the earlier proffer was based on Zytiga's high sales revenue but lacked evidence concerning Zytiga's market share. The only evidence Defendants provided concerning Zytiga's increasing market share was the fraudulent and misleading statements relating to Zytiga's growth in the chemo-naïve mCRPC market. Therefore, the single most reasonable explanation for the Patent Office's approval of the '438 Patent was Defendants' fraudulent and misleading statements concerning Zytiga's growth in the chemo-naïve mCRPC market.

87. Defendants made other misleading statements in their June 4, 2013 submission to the Patent Office, contrary to Defendants' duties of candor and good faith.

a. Defendants stated that Zytiga was "the most successful oral oncology launch in history." This was misleading because numerous non-oral cancer drugs have been far

more successful than Zytiga. Defendants knew this but failed to disclose the information to the Patent Office.

b. All drugs for treating mCRPC have short efficacy periods because the disease quickly becomes resistant to a given drug. In practice, this means that patients frequently switch medications. This suggests that any new mCRPC drug is likely to have some immediate commercial success. Therefore, the immediate commercial success of any new mCRPC drug is not necessarily unexpected or the result of innovation. Indeed, because mCRPC drugs have short efficacy periods, Zytiga's purported commercial success described by Defendants lacked the requisite nexus to the claimed invention in the '340 Application. Defendants knew these facts at the time they made their representations to the Patent Office. Nevertheless, Defendants failed to disclose them to the Patent Office, even though Defendants' duties of candor and good faith required such disclosure.

c. Zytiga earned high revenue for Defendants because it does not sequence well with its biggest competitor in the chemo refractory mCRPC market, Xtandi. This means Zytiga had a natural commercial advantage over Xtandi simply because Zytiga was approved and launched first. For this reason, Zytiga's purported commercial success described by Defendants lacked the requisite nexus to the claimed invention in the '340 Application. These facts were known by Defendants at the time they made their representations to the Patent Office. Nevertheless, Defendants failed to disclose them to the Patent Office, even though Defendants' duties of candor and good faith required such disclosure.

d. New urology guidelines for treatment of CRPC patients in 2013 indicated many factors that should guide a doctor's decision to prescribe one drug instead of another. Zytiga was recommended in some cases because it was the least toxic. This

recommendation was a significant factor explaining the high sales revenue for Zytiga, and it had nothing to do with the claimed innovation embodied in the '438 Patent (*i.e.,* the administration of abiraterone with prednisone). Defendants knew these facts at the time they made their representations to the Patent Office. Nevertheless, Defendants failed to disclose them to the Patent Office, even though Defendants' duties of candor and good faith required such disclosure.

e. The '213 Patent was a blocking patent that precluded generic entry or even meaningful research in abiraterone acetate by competing drug manufacturers prior to December 2016. Abiraterone acetate was one of the first of several new drugs for the mCRPC market that were approved and introduced beginning in or around 2010. Abiraterone acetate was the first major new drug that could be orally administered. Therefore, the '213 Patent casts substantial doubt that Zytiga's high sales revenues after launch resulted from the claimed innovation in the '438 Patent. This is a material fact that was known by Defendants and should have been disclosed to the Patent Office, particularly since the Patent Office and the courts have repeatedly stressed the importance of a blocking patent when determining whether a drug's commercial success obviates a finding of obviousness. *See, e.g.*, *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005) ("Because market entry by others was precluded [due to patent protection and statutory exclusivity], the inference of non-obviousness . . . from evidence of commercial success . . . is weak"); *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 740-41 (Fed. Cir. 2013) (same). Moreover, the '438 Patent is not a continuation of the '213 Patent, and thus the Examiners that considered each of the patent applications were not the same person. The Examiner for the '438 Patent was San-Ming Hui, whereas the Examiner for the '213 Patent was Anthony Bottino. The Examiner for the '438 Patent cannot

therefore be presumed to have been aware of the earlier blocking '213 Patent. Defendants failed to disclose the existence of the '213 Patent as a blocking patent to the Patent Office when pursing the '438 Patent, even though Defendants' duties of candor and good faith required such disclosure.

f. The '438 Patent claims the combination of abiraterone acetate and prednisone for the purpose of alleviating certain side-effects of abiraterone acetate, such as increased hypertension. However, drugs for mCRPC usually extend a patient's life by a few months, at best. Thus, alleviating side effects may not have actually been a factor in the decision to prescribe or take Zytiga as of 2013, when Defendants made their representations to the Patent Office. Accordingly, Defendants' statements regarding the commercial success of Zytiga misled the Patent Office about the required "nexus" between the commercial success of the drug and the patent, which is a requirement of showing commercial success as a secondary consideration under patent law. Defendants knew these facts at the time they made their representations to the Patent Office. Nevertheless, Defendants failed to disclose them to the Patent Office, even though Defendants' duties of candor and good faith required such disclosure.

g. Defendants stated to the Patent Office that, "Zytiga had almost 70% market share in July of 2012 for chemo refractory prostate cancer patients, just slightly over a year after ZYTIGA's initial approval, and despite the fact that a [*sic*] JEVTANA had been approved two years earlier." However, Zytiga is an oral medication, whereas Jevtana is a one-hour intravenous infusion. That distinction alone had an impact on Zytiga's purported success compared to Jevtana. Yet, Defendants did not disclose to the Patent Office that Zytiga's commercial success compared to Jevtana related to different routes of administration.

Importantly, neither the pending claims in the '340 Application nor the issued claims in the '438 Patent are limited to oral administration. On the contrary, the '438 Patent discloses embodiments for the claimed methods that can be administered intravenously. Thus, Defendants misleadingly withheld information showing that the required "nexus" between the patented claims and the purported commercial success did not exist. These facts were known by Defendants at the time Defendants made their representations to the Patent Office. Nevertheless, Defendants failed to disclose them to the Patent Office, even though Defendants' duties of candor and good faith required such disclosure.

h. Defendants did not disclose to the Patent Office that, in 2013, the price of Zytiga was considerably less than Xtandi and Jevtana. Xtandi cost approximately 35% more per year, and Jevtana cost approximately 50% more. These facts were known by Defendants at the time Defendants made their representations to the Patent Office. Nevertheless, Defendants failed to disclose them to the Patent Office, even though Defendants' duties of candor and good faith required such disclosure.

i. Zytiga is not always administered or prescribed with prednisone. The sales of Zytiga that are not co-administered with prednisone necessarily lack the required nexus to the '438 Patent, since the '438 Patent requires co-administration with prednisone to be infringed. Upon information and believe, abiraterone is prescribed and sold without prednisone at least 10% of the time. For these sales, there is no nexus to the '438 Patent. On information and belief, during prosecution of the '340 Application, Defendants were aware that at least 10% of Zytiga sales were prescribed or administered without the patented co-administration with prednisone. Thus, by failing to account for these sales that necessarily lacked a nexus to the '438 Patent, Defendants misleadingly inflated Zytiga's market share in

the course of describing the purported commercial success of the alleged invention in the '438 Patent. These facts were known by Defendants at the time Defendants made their representations to the Patent Office. Nevertheless, Defendants failed to disclose them to the Patent Office, even though Defendants' duties of candor and good faith required such disclosure.

88. In making each of these fraudulent or misleading statements to the Patent Office, Defendants knew that the evidence supposedly demonstrating Zytiga's commercial success was highly material to the issue of patentability of the claims in the '438 Patent.

89. In making each of these fraudulent or misleading statements to the Patent Office, each party or person making such submission did so as the agent on behalf of each of the Defendants, who were each interested parties to the '340 Application. Each Defendant jointly prosecuted the '438 Patent application for each of their individual and collective benefit.

90. Based on Defendants' false and misleading representations and reliance thereon, the Patent Office allowed the claims in the '340 Application and issued the '438 Patent.

91. Subsequent to the issuance of the '438 patent, there was a proceeding to correct inventorship in which Dr. Johann S. de Bono was added as an inventor to the '438 patent. BTG is the owner of Dr. de Bono's inventions and thus asserts co-ownership of the '438 patent along with Janssen.

C. Defendants Used the Fraudulently Obtained '438 Patent to Block Generic Competition

92. After fraudulently obtaining the '438 Patent, Defendants listed the patent in the Orange Book along with the '213 Patent. During all relevant times, Defendants listed in the Orange Book only two patents covering Zytiga: the '213 Patent, and the '438 Patent.

93. The ’213 Patent (which is directed to the compound, abiraterone acetate) expired on December 13, 2016, and the ’438 Patent will expire in approximately 2027. Thus, after December 13, 2016, only the ’438 Patent blocked generic competition for abiraterone acetate.

94. Prior to December 2016, numerous generic companies filed ANDAs with the FDA seeking approval to distribute a generic version of Zytiga. These companies include Actavis Laboratories, FL, Inc.; Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC; Apotex Inc. and Apotex Corp.; Amerigen Pharmaceutials Limited; Citron Pharma LLC; Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc.; Glenmark Pharmaceuticals Inc. and affiliated entities.; Hetero USA Inc. and affiliated entities; Mylan Pharmaceuticals Inc. and Mylan Inc.; Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc; Sun Pharmaceutical Industries Ltd. and Sun Pharmaceuticals Industries, Inc.; Teva Pharmaceuticals USA, Inc.; Wockhardt Bio A.G.; Wockhardt USA LLC and Wockhardt Ltd.; West-Ward Pharmaceutical Corp.; and Hikma Pharmaceuticals, LLC (collectively, the “ANDA Filers”).

95. The vast majority of the ANDA Filers filed their ANDAs in June and July 2015.

96. Given the unusual breadth of ANDA filings for Zytiga, over a dozen generic manufacturers would have been able to file Paragraph I, II, or III certifications and gain approval to introduce generic alternatives to Zytiga by December 2016, but for Defendants’ wrongful listing of the fraudulently obtained ’438 Patent in the Orange Book.

97. Defendants’ listing of the ’438 Patent in the Orange Book constituted a false and fraudulent statement to the U.S. government.

98. Because Defendants fraudulently obtained the '438 Patent and improperly listed it in the Orange Book, Defendants forced the ANDA Filers to file Paragraph IV certifications.

99. Defendants instituted objectively baseless litigation against the ANDA Filers, alleging infringement of Defendants' invalid, unenforceable, and fraudulently-obtained '438 Patent. By filing the infringement lawsuits, Defendants triggered the 30-month stays on FDA approval of the ANDA Filers' applications to market generic alternatives to Zytiga. Defendants commenced these sham litigations for the anticompetitive and unlawful purpose of delaying or preventing generic entry into the relevant market. Defendants knew at the time that there was no objective merit to these suits. Accordingly, Defendants have unlawfully but successfully blocked generics from entering the market since at least December 2016.

100. Because Defendants' fraudulent scheme alleged herein, tentative approval for the ANDA Filers have been wrongfully delayed. For example, tentative approval for the Wockhardt ANDA Filers was not granted by the FDA until October 18, 2017. The FDA granted tentative approval for the Amneal entities on October 27, 2017. But for Defendants' misconduct as alleged herein, one or more of the ANDA Filers would have been able to supply the commercial quantities of generic Zytiga necessary to supply the market since at least December 2016.

101. In January 2018, the PTAB invalidated the '438 Patent in a series of *inter partes* reviews brought by several generic drug makers. *Amerigen Pharms., Ltd. v. Janssen Oncology, Inc.*, IPR2016-00286 (P.T.A.B. Jan. 17, 2018); *Mylan Pharms., Inc. v. Janssen Oncology, Inc.*, IPR2016-01332 (P.T.A.B. Jan. 17, 2018); *Wockhardt Bio AG v. Janssen Oncology, Inc.*, IPR2016-01582 (P.T.A.B. Jan. 17, 2018). Defendants requested rehearing of the PTAB's Final

Written Decisions in February 2018. When the PTAB denied rehearing, Defendants appealed to the Federal Circuit.

102. On October 31, 2018, the United States District Court for the District of New Jersey (McNulty, J.) issued a Consolidated Opinion[2] determining—based on clear and convincing evidence—that the '438 Patent was invalid for obviousness. *See BTG Int'l Ltd. v. Amneal Pharm. LLC,* 352 F. Supp. 3d 352 (D.N.J. 2018). Defendants also appealed this decision to the Federal Circuit.

103. On May 14, 2019, in a consolidated appeal, the Federal Circuit affirmed the PTAB's Final Written Decision and the District Court's Consolidated Opinion of invalidity. *See BTG Int'l Ltd. v. Amneal Pharm. LLC,* 923 F.3d 1063 (Fed. Cir. 2019).

104. To date, because of the delays Defendants caused through their fraudulent scheme, no generic has yet entered the market.

105. Because of Defendants' false and misleading statements to the Patent Office in procuring the '438 Patent, and Defendants' subsequent assertion of the '438 Patent in sham litigation against generic competitors who were willing and able to introduce less-expensive alternatives sufficient to satisfy market demand, consumers have been deprived of, and continue to be deprived of, a lower-cost generic form of Zytiga from at least December 13, 2016.

D. Defendants' Fraudulent Extension of the Patent Monopoly Caused the Submission of False or Fraudulent Claims to Government Healthcare Programs

106. When an upstream fraud on the government taints claims for payment later submitted to the government, the claims are "false or fraudulent" within the meaning of the FCA. For example, if a government contractor obtains a contract by fraud, claims for

[2] The Consolidated Opinion determined the '438 Patent was invalid in three infringement actions brought by Janssen Biotech, Inc.; Janssen Oncology, Inc.; Janssen Research & Development, LLC; and BTG International Ltd. against various generic competitors in civil action Nos. 2:15-cv-05909-KM-JBC, 2:16-cv-02449-KM-JBC, and 2:17-cv-06435-KM-JBC.

payment later submitted under that contract are actionable under the FCA. Or if a manufacturer obtains FDA approval for a new drug by defrauding the FDA, then claims for payment for that drug are tainted by fraud and actionable under the FCA. It is also well-established that when drug manufacturers manipulate drug prices to the government's detriment, the resulting claims for payment are false or fraudulent.

107. Here, Defendants maintained their patent monopoly by defrauding the Patent Office, and each and every claim for payment submitted to the United States and the Plaintiff States during the unlawfully extended monopoly period (*i.e.*, after the '213 patent was due to expire in December 2016) is tainted by that upstream fraud and therefore actionable under the FCA and its state-law counterparts.

108. The link between the fraud on the Patent Office and false claims to the government is clear and direct. Indeed, the entire point of Defendants' fraud was to extend the patent monopoly on abiraterone acetate so that they could continue to charge inflated prices for Zytiga to all payors, including government healthcare programs, and so Defendants could ensure that all of the payments for abiraterone acetate—including all of the government payments—flowed to Defendants, and not generic competitors.

109. The unlawful exclusion of generic competitors is especially damaging to the government. Many government programs require patients to use or consider using generic alternatives before using more expensive name-brand drugs. Thus, each and every claim for payment or reimbursement for Zytiga that would have been substituted for a less expensive generic equivalent also constituted a False Claim.

110. Independently, Defendants directly defrauded government paying agencies by expressly and implicitly certifying to government payors that the price they were

charging the government for Zytiga was "fair and reasonable," or at least not tainted by fraud, when they knew that the price was actually the product of an unlawfully extended monopoly.

111. For a drug manufacturer to sell pharmaceutical products to the federal government under certain government programs—either directly through sales to a government agency, or indirectly by receiving reimbursement for sales through Medicaid—the manufacturer must enter into several agreements with the federal government in which the manufacturer reports prices and business practices that establish the purchase price or reimbursement amounts are "fair and reasonable" under federal acquisition regulations.

112. For Defendants to market Zytiga to federal agencies or otherwise qualify Zytiga for reimbursement under certain government programs, Defendants must list Zytiga's prices on the Federal Supply Schedule ("FSS"), a program run by the General Services Administration ("GSA"). To do so, Defendants would have been required to sign a standard Master Agreement ("MA") and a Pharmaceutical Price Agreement ("PPA"). *See* 38 U.S.C. § 8126 (a). The PPA must be renewed annually and include the non-federal average manufacturer price ("AMP") for the prior year. Moreover, drug manufacturers are required to update their AMP information to CMS every calendar quarter. *See* 42 C.F.R. § 414.804(a)(5). The AMP is used to calculate the Federal Ceiling Price ("FCP"), which is 76 percent of the AMP plus a discount pegged to the cost of living index. As part of this process, Defendants must periodically provide the federal government with Zytiga's commercial list price, the lowest price charged to any commercial customer (the "Most Favored Customer"), and the name and pricing information for a "Tracking Customer," which is the "customer or class of customers whose pricing is tracked against the awarded

FSS pricing for the purposes of ensuring that prices remain *fair and reasonable* throughout the life of the contract." (Emphasis added.)

113. As part of the GSA's assessment of Zytiga pricing, Defendants were required to supply a written justification for offered pricing, a mechanism for future potential pricing adjustments, and proof that the price is fair and reasonable. *See* About GSA Schedules, available at https://www.gsa.gov/buying-selling/purchasing-programs/gsa-schedules/about-gsa-schedules.

114. Drug manufacturers such as Defendants have an express obligation to provide truthful information about AMP pricing to the government, and such manufacturers may be subject to substantial penalties if they provide inaccurate AMP information. For example, the FSS Solicitation Document relating to drugs, pharmaceuticals & hematology related products provides that: "[a]ccuracy of information and computation of prices is the responsibility of the Contractor . . . . Inclusion of incorrect information will cause the Contractor to resubmit/correct and redistribute the Federal Supply Schedule Price List, and may constitute sufficient cause for Cancellation . . . and application of any other remedies as provided by law—including monetary recovery." GSA Drugs, Pharmaceuticals & Hematology Related Products Solicitation, 01 - Solicitation Document, pp. 39-40.

115. Moreover, to receive payment or reimbursement under Medicaid for Zytiga, Defendants must participate in the Medicaid Drug Rebate Program ("MDRP"). Under the MDRP, the manufacturer must submit product and pricing data for all of its drugs that are eligible for coverage under Medicaid to CMS *via* the Drug Data Reporting for Medicaid ("DDR") system. Under the agreement, the manufacturer must supply the AMP and the

number of units sold to DHHS. Drug manufacturers are required to provide truthful information and are subject to substantial civil penalties if they provide false information to the government. *See* 42 U.S.C. § 1396r-8(b)(3)(C)(ii). When providing the AMP to CMS, Defendants implicitly certify that the average manufacturer price reported has not been unlawfully inflated through the exclusion of competitors.

116. Defendants are also required to participate in the Section 340B Drug Pricing Program, administered by the Office of Pharmacy Affairs in the DHHS. Under this program, Defendants are required provide drugs to eligible health care organizations and certain other entities at reduced prices based on pricing data supplied to the federal government, including with respect to the foregoing information provided to the DHHS and the GSA through the DDR and FSS, respectively.

117. Defendants violated their obligations under these programs because the prices they negotiated with the government for Zytiga were based on illegally-obtained patent protection, and thus manifestly were not "fair and reasonable." Even if all of the data Defendants provided to the government was literally accurate, Defendants misleadingly omitted the critical fact that their pricing was the product of an unlawfully extended patent monopoly, *i.e.*, a fraud on the government. That omission goes directly to whether the prices the government paid for Zytiga were fair and reasonable.

118. Defendants, their employees and agents, individually and in concert, knowingly submitted or caused to be submitted False Claims to the United States Government and the Plaintiff States to secure payments for illegally inflated prices for abiraterone acetate.

119. The United States Government and the Plaintiff States were unaware of Defendants' fraudulent scheme, misrepresentations to the Patent Office, and wrongful listing of the '438 Patent in the Orange Book at the time they paid False Claims.

E. Defendants' Misrepresentations Were Material.

120. Defendants' misrepresentations were material—both to the Patent Office's decision to grant the '438 Patent, and to the government's subsequent payment decisions.

121. With respect to the Patent Office's determination, it is well-established that an application seeking a patent that is obvious over prior art should be rejected. It is also well-established that an applicant can surmount a *prima facie* finding of obviousness through secondary considerations of unexpected commercial success only if there is a nexus between the claimed invention and the commercial success. These principles were well-known by practitioners in the field, particularly Defendants. But for Defendants' misrepresentations to the Patent Office concerning Zytiga's purported commercial success as alleged herein, the Patent Office would never have issued the '438 Patent.

122. Defendants' fraud was also material to the government's payment decisions.

123. The price of a good that the government pays for is *per se* material to the government's payment decision. Had the price been less, the government would have paid less.

124. In this case, the government would have paid *a lot* less. The United States and the Plaintiff States have spent and continue to spend hundreds of millions of dollars on Zytiga every year. As noted by the FDA, studies have demonstrated that the entry of generics lower prices for the drug by 85% and quickly capture 90% of the market. Defendants prevented this from happening with Zytiga by applying for and obtaining the

'438 patent. But for this illegally acquired patent, generic competitors could have entered the market for abiraterone acetate even earlier, competing with Zytiga as early as December 2016, when the patent monopoly lawfully should have expired.

125. But for Defendants' fraudulent conduct, at least two groups of generic competitors would have introduced generic alternatives to Zytiga sufficient to have satisfied demand for the drug between December 2016 and October 2017. But for Defendants' unlawful conduct, competition would have lowered prices for abiraterone acetate by 85% percent or more, and lower-priced generics would have filled 90% of Zytiga prescriptions. Instead, Defendants have used their fraudulently-acquired patent to prevent generic competitors from marketing and selling lower-priced alternatives.

126. The government has repeatedly confirmed, by word and deed, that drug price manipulation is material to its payment decisions.

127. The government objects to the abuse of patents to exclude generic competitors. *See, e.g., FTC v. AbbVie Inc.*, No. 14-5151, 2018 U.S. Dist. LEXIS 109628 (E.D. Pa. June 29, 2018).

128. Government law enforcement views overcharging the government through anticompetitive conduct to be material and serious violation. For example, a Department of Justice press release dated November 14, 2018 in connection with guilty pleas by foreign companies for bid-rigging states: "'The FBI remains committed to holding corporations—both foreign and domestic—accountable for anticompetitive conduct and fraudulent practices toward the United States,' said FBI Executive Assistant Director Amy Hess."

129. As another example, on May 10, 2019, 43 states and Puerto Rico filed suit against over a dozen pharmaceutical manufacturers and their executives for artificially

inflating the price of generic drugs through anticompetitive conduct. *See State of Connecticut v. Teva Pharms. USA, Inc.*, No. 3:19-cv-00710-MPS (D. Conn. filed May 10, 2019).

130. As another example, the United States filed a criminal Information on May 30, 2019 against Heritage Pharmaceuticals Inc., in the Eastern District of Pennsylvania, 2:19-cr-00316-RBS, alleging that Heritage fixed the prices for a diabetes drug by suppressing and eliminating competition. In connection with the price-fixing allegations, Heritage agreed to pay over $7 million to settle the government's claims under the FCA.

131. In purchasing drugs or reimbursing for prescriptions as an end-payor for certain government programs, the United States Government and the Plaintiff States require manufacturers to report accurate prices to them for purposes of calculating the "fair and reasonable" price that the government will pay. Those calculations necessarily assume that the inputs given to the government are not tainted by upstream fraud that would inflate the price and cause the government to pay more than it otherwise would have.

132. The sole purpose of Defendants' fraud was to cause all payors—including the government healthcare programs that spend more than a billion dollars annually on this drug—to continue paying unlawful monopoly prices to Defendants, instead of fair prices determined by market competition. The inevitable and intended result was the gouging of the government and the unlawful enrichment of Defendants.

133. The government is ineligible to challenge the validity of patents in a post-issuance review before the PTAB. *See Return Mail, Inc. v. United States Postal Serv.*, No. 17-1594, 2019 WL 2412904, at *11 (U.S. June 10, 2019). Therefore, recovering through the FCA for overcharges paid by the government for drugs whose prices have been unlawfully inflated

as a result of fraudulently-obtained pharmaceutical patents is an important way for the government to protect healthcare funds from massive waste and fraud.

F. Defendants Acted With Requisite Knowledge

134. The FCA requires that the defendant have either actual knowledge of information (*e.g.*, that a claim is false) or acts with either deliberate ignorance or reckless disregard to the truth or falsity of the information.

135. Defendants acted with the requisite scienter when they misrepresented the supposed commercial success of Zytiga in prosecuting the '438 Patent. They actually knew or were reckless to the fact that the claimed commercial success of Zytiga was unrelated to any invention claimed in the '438 Patent, including the fact that Zytiga's most important competitor had not received FDA approval during the period of Defendants' market share comparison. Despite knowing these material facts, Defendants failed to disclose them to the Patent Office.

136. Defendants knew that the United States and the Plaintiff States would be purchasers and third-party payers for Zytiga through direct or indirect sales of Zytiga or the payment of claims for prescription drug reimbursement submitted by providers under government programs. Thus, they knew that their fraud on the Patent Office would cause false claims to be submitted to the United States and the Plaintiff States.

137. Defendants also had the requisite scienter when they submitted price information and subsequent claims for payment to the government. At all times, Defendants either actually knew, were deliberately indifferent to, or recklessly disregarded the fact that they had unlawfully extended their patent monopoly to inflate the price of Zytiga. Thus, Defendants knew that the pricing information they submitted to the government would not result in a price that was "fair and reasonable," and they knew that

the claims they were submitting (or causing others to submit) were false or fraudulent because they were for inflated prices. Defendants also knew that the claims they submitted or caused to be submitted for the payment or reimbursement of Zytiga were false or fraudulent because they sought payment for Zytiga prescriptions that would have been filled by a less expensive generics but for Defendants' unlawful exclusion of competitors.

138. In sum, this case does not involve a garden-variety attempt by a manufacturer to extend a patent monopoly. Defendants clearly and brazenly crossed legal and ethical lines while extending the patent monopoly for Zytiga. They withheld critical information from the Patent Office, and then exploited the wrongful extension of the patent monopoly to extract billions of dollars from the United States and the Plaintiff States.

VII. CLAIMS FOR RELIEF

Claim for Relief I
False Claims Act
31 U.S.C. §§ 3729–3733

139. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

140. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729–3733, as amended.

141. Through the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims for payment of Zytiga.

142. Defendants also knowingly used false records and statements material to false claims for payment for Zytiga.

143. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities

across the United States. Relator has no control over, or dealings with, such entities, and has no access to the records in their possession.

144. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the Government would not have paid but for Defendants' illegal conduct.

145. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

146. Additionally, the United States is entitled to a maximum penalty of up to $21,916 for each and every violation alleged herein.

Claim for Relief II
California False Claims Act
Cal. Gov't Code §§ 12650–12656

147. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

148. This is a claim for treble damages and penalties under the California False Claims Act.

149. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

150. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

151. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a

false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

152. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of California—through any state funded program, including, without limitation, Medicaid—for Zytiga.

153. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of California.

154. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of California. Relator has no control over or dealings with such entities and has no access to the records in their possession.

155. The State of California, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of California would not have paid but for Defendants' illegal conduct.

156. By reason of Defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

157. Additionally, the State of California is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

158. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of California pursuant to Cal. Gov't Code § 12652(c)(1).

Claim for Relief III
Colorado Medicaid False Claims Act
Colo. Rev. Stat. §§ 25.5-4-303.5 to -310

159. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

160. This is a claim for treble damages and penalties under the Colorado Medicaid False Claims Act.

161. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

162. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

163. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

164. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Colorado—through any state funded program, including, without limitation, Medicaid—for Zytiga.

165. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Colorado.

166. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities

across the State of Colorado. Relator has no control over or dealings with such entities and has no access to the records in their possession.

167. The State of Colorado, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Connecticut would not have paid but for Defendants' illegal conduct.

168. By reason of Defendants' acts, the State of Colorado has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

169. Additionally, the State of Colorado is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

170. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Colorado pursuant to Colo. Rev. Stat § 25.5-4-306(2).

Claim for Relief IV
Connecticut False Claims Act
Conn. Gen. Stat. §§ 4-274 to -289

171. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

172. This is a claim for treble damages and penalties under the Connecticut False Claims Act.

173. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

174. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

175. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

176. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Connecticut—through any state funded program, including, without limitation, Medicaid—for Zytiga.

177. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Connecticut.

178. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Connecticut. Relator has no control over or dealings with such entities and has no access to the records in their possession.

179. The State of Connecticut, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Connecticut would not have paid but for Defendants' illegal conduct.

180. By reason of Defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

181. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Connecticut pursuant to Conn. Gen. Stat. § 4-277.

Claim for Relief V
Delaware False Claims and Reporting Act
Del. Code Ann. tit. 6, §§ 1201–1211

182. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

183. This is a claim for treble damages and penalties under the Delaware False Claims and Reporting Act.

184. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

185. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

186. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

187. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Delaware—through any state funded program, including, without limitation, Medicaid—for Zytiga.

188. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Delaware.

189. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Delaware. Relator has no control over or dealings with such entities and has no access to the records in their possession.

190. The State of Delaware, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Delaware would not have paid but for Defendants' illegal conduct.

191. By reason of Defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

192. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Delaware pursuant to Del. Code Ann. tit. 6, § 1203(b).

Claim for Relief VI
Florida False Claims Act
Fla. Stat. §§ 68.081–.09

193. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

194. This is a claim for treble damages and penalties under the Florida False Claims Act.

195. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

196. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

197. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

198. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Florida—through any state funded program, including, without limitation, Medicaid—for Zytiga.

199. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Florida.

200. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Florida. Relator has no control over or dealings with such entities and has no access to the records in their possession.

201. The State of Florida, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Florida would not have paid but for Defendants' illegal conduct.

202. By reason of Defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

203. Additionally, the State of Florida is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

204. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Florida pursuant to Fla. Stat. § 68.083.

Claim for Relief VII
Georgia False Medicaid Claims Act
Ga. Code Ann. §§ 49-4-168 to -168.6

205. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

206. This is a claim for treble damages and penalties under the Georgia False Medicaid Claims Act.

207. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

208. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

209. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

210. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Georgia—through any state funded program, including, without limitation, Medicaid—for Zytiga.

211. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Georgia.

212. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Georgia. Relator has no control over or dealings with such entities and has no access to the records in their possession.

213. The State of Georgia, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Georgia would not have paid but for Defendants' illegal conduct.

214. By reason of Defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

215. Additionally, the State of Georgia is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

216. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Georgia pursuant to Ga. Code Ann. §49-4-168.

Claim for Relief VIII
Hawaii False Claims Act
Haw. Rev. Stat. §§ 661-21 to -31

217. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

218. This is a claim for treble damages and penalties under Hawaii False Claims Act.

219. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

220. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

221. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a

false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

222. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Hawaii—through any state funded program, including, without limitation, Medicaid—for Zytiga.

223. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Hawaii.

224. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Hawaii. Relator has no control over or dealings with such entities and has no access to the records in their possession.

225. The State of Georgia, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Hawaii would not have paid but for Defendants' illegal conduct.

226. By reason of Defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

227. Additionally, the State of Hawaii is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

228. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Hawaii pursuant to Haw. Rev. Stat. § 661-25.

Claim for Relief IX
Illinois False Claims Act
740 Ill. Comp. Stat. 175/1–175/8

229. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

230. This is a claim for treble damages and penalties under the Illinois False Claims Act.

231. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

232. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

233. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

234. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Illinois—through any state funded program, including, without limitation, Medicaid—for Zytiga.

235. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Illinois.

236. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities

across the State of Illinois. Relator has no control over or dealings with such entities and has no access to the records in their possession.

237. The State of Illinois, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Illinois would not have paid but for Defendants' illegal conduct.

238. By reason of Defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

239. Additionally, the State of Illinois is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

240. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Illinois pursuant to 740 Ill. Comp. Stat. 175/4(b).

Claim for Relief X
Indiana False Claims and Whistleblower Protection Act
Ind. Code §§ 5-11-5.5-1 to -18

241. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

242. This is a claim for treble damages and penalties under the Indiana False Claims and Whistleblower Protection Act.

243. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

244. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

245. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

246. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Indiana—through any state funded program, including, without limitation, Medicaid—for Zytiga.

247. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Indiana.

248. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Indiana. Relator has no control over or dealings with such entities and has no access to the records in their possession.

249. The State of Indiana, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Indiana would not have paid but for Defendants' illegal conduct.

250. By reason of Defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

251. Additionally, the State of Indiana is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

252. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Indiana pursuant to Ind. Code § 5-11-5.5-4.

Claim for Relief XI
Iowa False Claims Act
Iowa Code §§ 685.1–.7

253. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

254. This is a claim for treble damages and penalties under the Iowa False Claims Act.

255. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

256. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

257. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

258. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Iowa—through any state funded program, including, without limitation, Medicaid—for Zytiga.

259. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Iowa.

260. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities

across the State of Iowa. Relator has no control over or dealings with such entities and has no access to the records in their possession.

261. The State of Iowa, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Iowa would not have paid but for Defendants' illegal conduct.

262. By reason of Defendants' acts, the State of Iowa has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

263. Additionally, the State of Iowa is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

264. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Iowa pursuant to Iowa Code § 685.3(2).

Claim for Relief XII
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. Ann. §§ 46:437–:440

265. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

266. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law.

267. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

268. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

269. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

270. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Louisiana—through any state funded program, including, without limitation, Medicaid—for Zytiga.

271. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Louisiana.

272. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Louisiana. Relator has no control over or dealings with such entities and has no access to the records in their possession.

273. The State of Louisiana, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Louisiana would not have paid but for Defendants' illegal conduct.

274. By reason of Defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

275. Additionally, the State of Louisiana is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

276. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Louisiana pursuant to La. Rev. Stat. Ann. § 46:439.1.

Claim for Relief XIII
Maryland False Health Claims Act
Md. Code Ann., Health-Gen. §§ 2-601 to -611

277. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

278. This is a claim for treble damages and penalties under the Maryland False Health Claims Act.

279. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

280. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

281. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

282. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Maryland—through any state funded program, including, without limitation, Medicaid—for Zytiga.

283. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Maryland.

284. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities

across the State of Maryland. Relator has no control over or dealings with such entities and has no access to the records in their possession.

285. The State of Maryland, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Maryland would not have paid but for Defendants' illegal conduct.

286. By reason of Defendants' acts, the State of Maryland has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

287. Additionally, the State of Maryland is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

288. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Maryland pursuant to Md. Code Ann., Health-Gen. § 2-604(a)(1).

Claim for Relief XIV
Massachusetts False Claims Act
Mass. Gen. Laws ch. 12, §§ 5A–5O

289. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

290. This is a claim for treble damages and penalties under the Massachusetts False Claims Act.

291. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

292. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

293. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

294. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the Commonwealth of Massachusetts—through any state funded program, including, without limitation, Medicaid—for Zytiga.

295. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the Commonwealth of Massachusetts.

296. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the Commonwealth of Massachusetts. Relator has no control over or dealings with such entities and has no access to the records in their possession.

297. The Commonwealth of Massachusetts, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the Commonwealth of Massachusetts would not have paid but for Defendants' illegal conduct.

298. By reason of Defendants' acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

299. Additionally, the Commonwealth of Massachusetts is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

300. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the Commonwealth of Massachusetts pursuant to Mass. Gen. Laws. ch. 12, § 5C(2).

Claim for Relief XV
Michigan Medicaid False Claims Act
Mich. Comp. Laws §§ 400.601–.615

301. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

302. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act.

303. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

304. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

305. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

306. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Michigan—through any state funded program, including, without limitation, Medicaid—for Zytiga.

307. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Michigan.

308. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Michigan. Relator has no control over or dealings with such entities and has no access to the records in their possession.

309. The State of Michigan, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Michigan would not have paid but for Defendants' illegal conduct.

310. By reason of Defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

311. Additionally, the State of Michigan is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

312. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Michigan pursuant to Mich. Comp. Laws § 400.610a.

Claim for Relief XVI
Minnesota False Claims Act
Minn. Stat. §§ 15C.01–.16

313. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

314. This is a claim for treble damages and penalties under the Minnesota False Claims Act.

315. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

316. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

317. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

318. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Minnesota—through any state funded program, including, without limitation, Medicaid—for Zytiga.

319. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Minnesota.

320. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Minnesota. Relator has no control over or dealings with such entities and has no access to the records in their possession.

321. The State of Minnesota, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Minnesota would not have paid but for Defendants' illegal conduct.

322. By reason of Defendants' acts, the State of Minnesota has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

323. Additionally, the State of Minnesota is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

324. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Minnesota pursuant to Minn. Stat. § 15C.05.

Claim for Relief XVII
Montana False Claims Act
Mont. Code Ann. §§ 17-8-401 to -413

325. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

326. This is a claim for treble damages and penalties under the Montana False Claims Act.

327. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

328. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

329. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

330. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Montana—through any state funded program, including, without limitation, Medicaid—for Zytiga.

331. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Montana.

332. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Montana. Relator has no control over or dealings with such entities and has no access to the records in their possession.

333. The State of Montana, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Montana would not have paid but for Defendants' illegal conduct.

334. By reason of Defendants' acts, the State of Montana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

335. Additionally, the State of Montana is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

336. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Montana pursuant to Mont. Code Ann. § 17-8-406.

Claim for Relief XVIII
Nevada Submission of False Claims to State or Local Government
Nev. Rev. Stat. §§ 357.010–.250

337. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

338. This is a claim for treble damages and penalties under the Nevada statute relating to the Submission of False Claims to State or Local Government, Nev. Rev. Stat. §§ 357.010–.250

339. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

340. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

341. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

342. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Nevada—through any state funded program, including, without limitation, Medicaid—for Zytiga.

343. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Nevada.

344. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Nevada. Relator has no control over or dealings with such entities and has no access to the records in their possession.

345. The State of Nevada, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Nevada would not have paid but for Defendants' illegal conduct.

346. By reason of Defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

347. Additionally, the State of Nevada is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

348. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Nevada pursuant to Nev. Rev. Stat. § 357.080.

Claim for Relief XVIX
New Jersey False Claims Act
N.J. Stat. Ann. §§ 2A:32C-1 to -18

349. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

350. This is a claim for treble damages and penalties under the New Jersey False Claims Act.

351. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

352. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

353. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

354. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of New Jersey—through any state funded program, including, without limitation, Medicaid—for Zytiga.

355. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of New Jersey.

356. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of New Jersey. Relator has no control over or dealings with such entities and has no access to the records in their possession.

357. The State of New Jersey, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of New Jersey would not have paid but for Defendants' illegal conduct.

358. By reason of Defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

359. Additionally, the State of New Jersey is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

360. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of New Jersey pursuant to N.J. Stat. Ann. § 2A:32C-5.

Claim for Relief XX
New Mexico Medicaid False Claims
N.M. Stat. Ann. §§ 27-14-1 to -15

361. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

362. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act.

363. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

364. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

365. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

366. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of New Mexico—through any state funded program, including, without limitation, Medicaid—for Zytiga.

367. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of New Mexico.

368. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of New Mexico. Relator has no control over or dealings with such entities and has no access to the records in their possession.

369. The State of New Mexico, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of New Mexico would not have paid but for Defendants' illegal conduct.

370. By reason of Defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

371. Additionally, the State of New Mexico is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

372. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of New Mexico pursuant to N.M. Stat. Ann. § 27-14-8.

Claim for Relief XXI
New Mexico Fraud Against Taxpayers Act
N.M. Stat. Ann. §§ 44-9-1 to -14

373. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

374. This is a claim for treble damages and penalties under the New Mexico Fraud Against Taxpayers Act.

375. Through the acts described herein, Defendants knowingly, intentionally, and willfully violated the New Mexico Fraud Against Taxpayers Act.

376. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of New Mexico pursuant to N.M. Stat. Ann. § 44-9-5.

Claim for Relief XXII
New York False Claims Act
N.Y. State Fin. Law §§ 187–194

377. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

378. This is a claim for treble damages and penalties under the New York False Claims Act.

379. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

380. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

381. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

382. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of New York—through any state funded program, including, without limitation, Medicaid—for Zytiga.

383. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of New York.

384. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of New York. Relator has no control over or dealings with such entities and has no access to the records in their possession.

385. The State of New York, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of New York would not have paid but for Defendants' illegal conduct.

386. By reason of Defendants' acts, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

387. Additionally, the State of New York is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

388. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of New York pursuant to N.Y. State Fin. Law § 190(2).

Claim for Relief XXIII
North Carolina False Claims Act
N.C. Gen. Stat. §§ 1-605 to -618

389. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

390. This is a claim for treble damages and penalties under the North Carolina False Claims Act.

391. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

392. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

393. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a

false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

394. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of North Carolina—through any state funded program, including, without limitation, Medicaid—for Zytiga.

395. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of North Carolina.

396. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of North Carolina. Relator has no control over or dealings with such entities and has no access to the records in their possession.

397. The State North Carolina, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of North Carolina would not have paid but for Defendants' illegal conduct.

398. By reason of Defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

399. Additionally, the State of North Carolina is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

400. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of North Carolina pursuant to N.C. Gen. Stat. § 1-608(b).

Claim for Relief XXIV
Oklahoma Medicaid False Claims Act
Okla. Stat. tit. 63, §§ 5053–5053.7

401. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

402. This is a claim for treble damages and penalties under the Oklahoma False Claims Act.

403. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

404. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

405. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

406. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Oklahoma—through any state funded program, including, without limitation, Medicaid—for Zytiga.

407. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Oklahoma.

408. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities

across the State of Oklahoma. Relator has no control over or dealings with such entities and has no access to the records in their possession.

409. The State of Oklahoma, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Oklahoma would not have paid but for Defendants' illegal conduct.

410. By reason of Defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

411. Additionally, the State of Oklahoma is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

412. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Oklahoma pursuant to Okla. Stat. tit. 63, § 5053.3.

Claim for Relief XXV
Rhode Island False Claims Act
R.I. Gen. Laws §§ 9-1.1-1 to -9

413. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

414. This is a claim for treble damages and penalties under the Rhode Island False Claims Act.

415. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

416. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

417. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

418. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Rhode Island—through any state funded program, including, without limitation, Medicaid—for Zytiga.

419. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Rhode Island.

420. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Rhode Island. Relator has no control over or dealings with such entities and has no access to the records in their possession.

421. The State of Rhode Island, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Rhode Island would not have paid but for Defendants' illegal conduct.

422. By reason of Defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

423. Additionally, the State of Rhode Island is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

424. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Rhode Island pursuant to R.I. Gen. Laws § 9-1.1-4(b).

Claim for Relief XXVI
Tennessee Medicaid False Claims Act
Tenn. Code Ann. §§ 7-5-181 to -185

425. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

426. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Act.

427. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

428. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

429. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

430. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Tennessee—through any state funded program, including, without limitation, Medicaid—for Zytiga.

431. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Tennessee.

432. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities

across the State of Tennessee. Relator has no control over or dealings with such entities and has no access to the records in their possession.

433. The State of Tennessee, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Tennessee would not have paid but for Defendants' illegal conduct.

434. By reason of Defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

435. Additionally, the State of Tennessee is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

436. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Tennessee pursuant to Tenn. Code Ann. § 71-5-183(b).

Claim for Relief XXVII
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. §§ 36.001–.132

437. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

438. This is a claim for double damages and penalties under the Texas Medicaid Fraud Prevention Law.

439. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

440. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

441. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

442. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Texas—through any state funded program, including, without limitation, Medicaid—for Zytiga.

443. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Texas.

444. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Texas. Relator has no control over or dealings with such entities and has no access to the records in their possession.

445. The State of Texas, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Texas would not have paid but for Defendants' illegal conduct.

446. By reason of Defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

447. Additionally, the State of Texas is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

448. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Texas pursuant to Tex. Hum. Res. Code Ann. § 36.101.

Claim for Relief XXVIII
Vermont False Claims Act
Vt. Stat. Ann. tit. 32, §§ 630–642

449. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

450. This is a claim for treble damages and penalties under the Vermont False Claims Act.

451. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

452. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

453. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

454. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Vermont—through any state funded program, including, without limitation, Medicaid—for Zytiga.

455. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Vermont.

456. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities

across the State of Vermont. Relator has no control over or dealings with such entities and has no access to the records in their possession.

457. The State of Vermont, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Vermont would not have paid but for Defendants' illegal conduct.

458. By reason of Defendants' acts, the State of Vermont has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

459. Additionally, the State of Vermont is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

460. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Vermont pursuant to Vt. Stat. Ann. tit. 32, § 632(b)(1).

Claim for Relief XXIX
Virginia Fraud Against Taxpayers Act
Va. Code Ann. §§ 8.01-216.1 to .19

461. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

462. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

463. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

464. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

465. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

466. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the Commonwealth of Virginia—through any state funded program, including, without limitation, Medicaid—for Zytiga.

467. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the Commonwealth of Virginia.

468. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the Commonwealth of Virginia. Relator has no control over or dealings with such entities and has no access to the records in their possession.

469. The Commonwealth of Virginia, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the Commonwealth of Virginia would not have paid but for Defendants' illegal conduct.

470. By reason of Defendants' acts, the Commonwealth of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

471. Additionally, the Commonwealth of Virginia is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

472. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the Commonwealth of Virginia pursuant to Va. Code Ann. § 8.01-216.5(a).

Claim for Relief XXX
Washington State Medicaid Fraud False Claims Act
Wash. Rev. Code §§ 74.66.005–.130

473. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

474. This is a claim for treble damages and penalties under the Washington State Medicaid Fraud False Claims Act.

475. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

476. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

477. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

478. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Washington—through any state funded program, including, without limitation, Medicaid—for Zytiga.

479. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Washington.

480. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Washington. Relator has no control over or dealings with such entities and has no access to the records in their possession.

481. The State of Washington, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Washington would not have paid but for Defendants' illegal conduct.

482. By reason of Defendants' acts, the State of Washington has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

483. Additionally, the State of Washington is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

484. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Washington pursuant to Wash. Rev. Code § 74.66.050.

Claim for Relief XXXI
The District of Columbia False Claims Law
D.C. Code §§ 2-381.01 to .09

485. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

486. This is a claim for treble damages and penalties under the District of Columbia False Claims Law.

487. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

488. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

489. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

490. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the District of Columbia—through any state funded program, including, without limitation, Medicaid—for Zytiga.

491. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the District of Columbia.

492. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the District of Columbia. Relator has no control over or dealings with such entities and has no access to the records in their possession.

493. The District of Columbia, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that District of Columbia would not have paid but for Defendants' illegal conduct.

494. By reason of Defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

495. Additionally, the District of Columbia is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the

relevant statutes.

496. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the District of Columbia pursuant to D.C. Code § 2-308.15(b)(1).

PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment against Defendants as follows:

A. That Defendants cease and desist from violating 31 U.S.C. §§ 3729–3733, and the relevant parts of each statute applicable to the Plaintiff States as set forth above;

B. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $21,916 for each violation of 31 U.S.C. §§ 3729–3733;

C. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of California has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the California False Claims Act, Cal. Gov't Code §§ 12650–12656;

D. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Colorado has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Colorado Medicaid False Claims Act, Colo. Rev. Stat §§ 25.5-4-303.5 to -310;

E. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Connecticut has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Connecticut False Claims Act, Conn. Gen. Stat. §§ 4-274 to -289;

F. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§ 1201–1211;

G. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Florida False Claims Act, Fla. Stat. §§ 68.081–.09;

H. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 to -168.6;

I. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 to -31;

J. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Illinois False Claims Act, 740 Ill. Comp. Stat. 175/1–175/8;

K. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of Defendants'

actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Indiana False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.5-1 to -18;

L. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Iowa has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of Iowa False Claims Act, Iowa Code §§ 685.1–.7;

M. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. §§ 46:437–:440;

N. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Maryland has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Maryland False Health Claims Act, Md. Code Ann., Health-Gen. §§ 2-601 to -611;

O. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages Commonwealth of Massachusetts has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, §§ 5A–5O;

P. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Michigan Medicaid False Claims Act, Mich. Comp. Laws. §§ 400.601–.615;

Q. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Minnesota has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Minnesota False Claims Act, Minn. Stat, §§ 15C.01–.16;

R. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Montana has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 to -413;

S. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Nevada statute concerning Submission of False Claims to State or Local Government, Nev. Rev. Stat. §§ 357.010–.250;

T. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 to -18;

U. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 to -15; and the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 to -14.

V. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New York has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the New York False Claims Act, N.Y. State Fin. Law §§ 187–194;

W. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of North Carolina has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 to -618;

X. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, §§ 5053–5053.7;

Y. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Rhode Island False Claims Act, R.I. Gen. Laws §§ 9-1.1-1 to -9;

Z. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 to -185;

AA. That this Court enter judgment against Defendants in an amount equal to two times the amount of damages the State of Texas has sustained because of Defendants' actions,

plus a civil penalty for the maximum amount allowed by statute, for each violation of the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001–.132;

BB. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Vermont has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Vermont False Claims Act, Vt. Stat. Ann. tit. 32, §§ 630–642;

CC. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the Commonwealth of Virginia has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 to .19;

DD. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Washington has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Washington State Medicaid Fraud False Claims Act, Wash. Rev. Code §§ 74.66.005–.130;

EE. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the District of Columbia False Claims Act, D.C. Code §§ 2-381.01 to .09;

FF. That Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d), and the relevant provisions of each statute applicable to the Plaintiff States as set forth above;

GG. That Relator be awarded all costs of this action;

HH. That the Relator be awarded reasonable attorneys' fees; and

II. That Relator recover such further and other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

LITE DEPALMA GREENBERG, LLC

Dated: June 20, 2019

s/ Bruce D. Greenberg

Bruce D. Greenberg
570 Broad Street, Suite 1201
Newark, NJ 07102
Telephone: (973) 623-3000
Facsimile: (973) 623-0858
bgreenberg@litedepalma.com

HERRERA PURDY LLP
Nicomedes Sy Herrera
(*pro hac vice* application to be filed)
Andrew Purdy (*pro hac vice* application to be filed)
Laura E. Seidl (*pro hac vice* application to be filed)
1300 Clay Street, Suite 600
Oakland, California 94612
Telephone: (510) 422-4700
NHerrera@HerreraPurdy.com
APurdy@HerreraPurdy.com
LSeidl@HerreraPurdy.com

GOLDSTEIN & RUSSELL, P.C.
Tejinder Singh (*pro hac vice* application to be filed)
7475 Wisconsin Avenue, Suite 850
Bethesda, Maryland 20814
Telephone: (202) 362-0636
TSingh@goldsteinrussell.com

Attorneys for Plaintiff-Relator Zachary Silbersher